K080698

SENORX

MAR 31 2008

7. 510(K) SUMMARY

Date prepared	March 10, 2008
Name	SenoRx, Inc. 11 Columbia Aliso Viejo, CA 92656 T. 949.362.4800; F. 949.362.0300
Contact person	Eben Gordon Vice President, RA/QA SenoRx, Inc. T. 949.362.4800; F. 949.362.0300
Device name	Gel Mark UltraCor Biopsy Site Marker
Common name	Biopsy site marker
Classification name	Implantable Clip
Classification regulation	878.4300 NEU
Predicate device	Biopsy Site Marker; K011402; clearance date 7/16/2001; FZP Gel Mark IV Tissue Marker, K040706, clearance date 4/8/2004, NEU
Description	The Gel Mark UltraCor Breast Biopsy Marker consists of a 17 Ga disposable beveled needle Applicator containing: • 2 resorbable polylactic acid/polyglycolic acid pellets. • 1 gold marker in the center position. • 1 polyethylene glycol (PEG) plug in the needle bevel. The gold marker is intended for long-term radiographic marking of the tissue site. The pellets are visible via ultrasound for approximately 4 weeks and are essentially resorbed in approximately 12 weeks. The Applicator has a beveled 20 cm needle with 1 cm depth marks and a locking plunger. The pellets are deployed from the beveled needle tip into the tissue site.
Indications for use	The Gel Mark UltraCor Biopsy Site Marker is indicated for use to radiographically mark breast tissue during a percutaneous breast biopsy procedure.
Summary of substantial equivalence	The Gel Mark UltraCor Biopsy Site Marker as the following similarities to the previously cleared predicate devices: • Same indications for use; • Same intended treatment site; • Same operating principle; and • Same basic design. Preclinical testing had confirmed the radiographic visibility of the gold marker. Gold, as a long-term implant, has an extensive history of use and has been cleared for use in a similar application. The resorbable polyethylene glycol plug has been used previously in SenoRx biopsy site markers to contain pellets in the applicator. The change to a metallic (stainless steel) applicator shaft is similar to the metallic (titanium) of a previous cleared SenoRx device. The reduction in the applicator shaft diameter varies in a manner that has no impact on device safety. In summary, the Gel Mark UltraCor Biopsy Sire Marker as described in this submission is substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 31 2008

SenoRx, Inc.
% Eben Gordonese
VP, Regulatory Affairs &
Quality Assurance
11 Columbia
Aliso Viejo, California 92656

Re: K080698
Trade/Device Name: Gel Mark UltraCor Biopsy Site Marker
Regulation Number: 21 CFR 878.4300
Regulation Name: Surgical mesh
Regulatory Class: II
Product Code: NEU
Dated: March 10, 2008
Received: March 12, 2008

Dear Mr. Mazzarese:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

6. INDICATIONS FOR USE

510(k) Number (if known): K080698

Device Name: _____ Gel Mark UltraCor Biopsy Site Marker _____

Indications for Use:

The Gel Mark UltraCor Biopsy Site Marker is indicated for use to radiographically mark breast tissue during a percutaneous breast biopsy procedure.

Prescription Use ___X____ AND/OR Over the Counter Use _____

(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Mark N Milhous Page 1 of 1

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K080698